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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/458,998	12/10/99	MOORE	N

EXAMINER	
HINES, T	
ART UNIT	PAPER NUMBER
1645	

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MARY HELEN SEARS
THE M H SEARS LAW FIRM CHARTERED
910 SEVENTEENTH STREET NW SUITE 800
WASHINGTON DC 20006

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/458,998	MOORE ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 May 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Amended claim 1 has been entered as filed on May 14, 2001. Claims 1-9 are pending in this office action.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Response to Arguments

3. Applicant's arguments filed May 14, 2001 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling is maintained. Applicant argues that application 09/139,720 teaches detailed preparation of antibodies specific to O-carbohydrate antibodies of *Legionella pneumophila*. It is understood that 09/139,720 is incorporated by reference. The specification on page 4 at line 10-12 states that " applicants the developed a modified enzyme immunoassay ("EIA") using a coated tube in which *L. pneumophila* serogroup 1 raw polyclonal antibodies that have been purified according to the affinity purification procedure described and claimed in the parent application." Therefore, the antibodies and procedures disclosed in 09/139,720 are what is used in the instant application. Therefore, the claims of the instant application, need to claim the same antibodies and procedures as found in 09/139,720. Claims 1-9 of the instant application do not require the uses of antibodies specific to O-carbohydrate of *Legionella pneumophila.* Claims 1-9 do not recite the use the O-polysaccharide antigen sample. Claims 1-9 of the instant application are not commensurate in scope with the examples taught in the specification of 09/139,720 for the following reasons.

A) Specification 09/139,720 teaches extraction steps in the examples which is critical and essential to the practice of the invention in the instant application. However claims 1-9 do not recite an extraction step. The extraction step is required to expose the O-polysaccharide of *Legionella*.

B) Specification 09/139,720 requires conjugation and coupling of the O-polysaccharide antigen to the chromatographic column and further requires affinity purification of the antibodies

to the O-polysaccharide antigen. The O-polysaccharide antigen must be present, then the antigen specific Legionella antibodies will bind and detect the presence of *Legionella*. However, the claims of the instant application do not recite the conjugation or coupling step, nor the affinity purification step. Claims 1-9 do not recite a preparation or pre-treatment step to make a O-polysaccharide antigen within the sample possibly containing *Legionella*.

Therefore, the claims do not include the limitations taught by the parent specification, thus they are not enabled.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Applicants argue that the action is not understood. Applicant states that the invention is using the purified antigen specific antibodies to *L. pneumophila* in any known enzyme immunoassay and the invention is not the enzyme immunoassay. However, claim 1 is drawn to an enzyme immunoassay of either the sandwich or competitive type for the detection of *L. pneumophila* in water. Claim 1 does not claim the use of the O-polysaccharide antigen and antibodies which applicant states is the inventive concept. Immunoassays must have steps that recite how the immunoassay is performed. There are no steps which recite how the enzyme immunoassay is performed. No step is taught for contacting a sample containing the antigen of interest with antibody. There is no detection step to detect the detecting agents. There is no step

which correlates detection of antigen-antibody complex to the presence of *Legionella pneumophila.* Therefore the rejection is maintained.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, is maintained. Applicant argues that there is no mystery about how enzyme labels are attached to antibodies and that any enzyme label may be conjugated to the antibodies. However, if applicant wants the antibody to be attached to the enzyme, then applicant needs to amend the claims to positively recite this step. The claims are interpreted in light of the specification, however limitations from the specification are not read into the claims. Therefore the claims requires these positive recitation of the required steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in further view of Strosberg et al (US Patent 4,780,407) is maintained.

8. Applicant argues that Strosberg et al., does not show a highly useful in detecting *Legionella* bacteria and that the references do not show what epitope the monoclonal antibodies bind too. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Claims 1-9 do not state a particular epitope or binding region on the *Legionella pneumophila*. Strosberg et al., teaches monoclonal antibodies to *Legionella pneumophila* serotype I purified by an affinity column to be used to detect bacteria in environmental water samples. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Applicants arguments that the monoclonal antibodies of Strosberg et al., "... have achieved no recognition in the real world of actual testing..." is without merit. Applicant has not provided any data which shows that the monoclonal antibody does not bind Legionella pneumophila serotype I. Mere statements to the contrary are not persuasive.

10. Applicants argue that adjusting the amount of polyclonal antibodies to L. pneumophila serogroup I could not produce the result disclosed and claimed in the present application. However, no more then routine skill in involved in adjusting the amount of a component such as water or antibody in the claimed process to suit a particular starting material in order to achieve the results taught in the prior art. *Ex parte Rasussen* (POBA 1959) 123 USPQ 498. Further, changes in concentration or other process conditions of an old process do not impart patentability

unless they produce a new unexpected result. Applicant has not pointed to a new unexpected result.

11. In response to applicant's arguments against the references individually, i.e., that Imrich teaches a "broad brush" of immunoglobulins, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Imrich et al., teaches using enzyme immunoassay detection methods. Imrich et al., teaches species-specific antigen of many pathogenic organisms require pretreatment prior to detect, like *Legionella pneumophila*, and it may be detected by non-serotype monoclonal antibodies after pretreatment with detergents and other reagents. Furthermore, Imrich et al., teaches the enzyme label may be soluble or particulate and may include dyed immunoglobulins binding substances such as dyes, polymers, latex beads, metallic sols or horse radish peroxidase. However, even though Imrich et al., may not teach the specific antibody, it is combined with references that teach the antibody. Therefore, it would have been obvious at the time of applicants invention to detect *Legionella* using detection methods taught by Imrich et al., where the monoclonal antibodies were obtained by techniques taught by taught by Strosberg et al., and combined with the antibody techniques of Cuatrecasas et al., because Strosberg et al., teaches the *Legionella* monoclonal antibodies can detected the bacteria in water samples.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in view of Strosberg et al (US Patent 4,780,407) in further view of Yen et al. (US Patent 4,206,094) is maintained. Imrich et al., Cuatrecasas et al., and Strosberg et al., have been discussed above. Applicant argues that they do not claim to have invented spacer molecules or magnetic micro spheres. Therefore, no more then routine skill is required to use finely divided metallic magnetic particles in a manner as taught in the art by Yen et al., in a method to detect *Legionella* taught by Imrich et al., Cuatrecasas et al., and Strosberg et al., because Yen et al., teaches the particles eliminate the necessity to bind radioactive or fluorescent tags and the particles are hydrophillic, stable, biocompatible and have good mechanical strength.

13. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al. (US Patent 4,411,832) in view of Strosberg et al (US Patent 4,780,407) and in further view of Jurgens et al., is maintained. Imrich et al.,Cuatrecasas et al., and Strosberg et al., have been discussed above. Applicant argues that Jurgens is concerned with raw antibodies having no antigen specificity and the results have no clear relationship to any work by applicants. However claim 8 is drawn to bacterium detected is another serotype of L. pneumophila and the purified antibodies are to the same serotype. Jurgens et al., teaches cross-reacting lipopolysaccharide (LPS) antigens in *Legionella pneumophila* serotypes 1 to 14. Furthermore, Imrich et al.(US Patent 5,415,994) in view of Cuatrecasas et al.

(US Patent 4,411,832) in view of Strosberg et al (US Patent 4,780,407) and in further view of Jurgens et al., teaches a rapid enzyme immunoassay capable of detecting other serotypes of Legionella. Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Thus, it would have been obvious at the time of applicants invention to have used antibodies from the known LPS antigen from serotype 5 which cross reacts with serotypes 1 to 14 as taught by Jurgens et al., with the well known method for detection of *Legionella* taught by Imrich et al., where the antibodies were purified using well known affinity chromatography techniques as taught by Cuatrecasas et al., in water samples as taught by Strosberg et al., because Jurgens et al., teaches that these antibodies react only with *L. pneumophila* serotypes and not with other *Legionella* species or other gram-negative bacteria.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

July 30, 2001

7/30/01

JENNIFER E. GRASER
PRIMARY EXAMINER